



Atty. Dkt. No. 074129-0510
(For 1653
S)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Shigeru Kamei et al.

Title: SUSTAINED-RELEASE PREPARATION

Appl. No.: 10/025,967

Filing Date: 12/26/2001

Examiner: D. Lukton

Art Unit: 1653

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(c), before the mailing date of either a final action under 37 CFR §1.113, a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application.

06/20/2005 SDENB0B1 00000035 10025967

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RELEVANCE OF EACH DOCUMENT

The documents are either in English or are presented with an English abstract or partial translation. English translations of the foreign-language documents are not readily available. However, the absence of such translation does not relieve the PTO from its duty to consider the submitted foreign language documents (37 CFR §1.98 and MPEP §609). English-language abstracts are attached.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

FEE

A fee in connection with submission of an information disclosure statement under 37 CFR §1.97(c) in the amount of \$180.00 in accordance with 37 CFR §1.17(p) is attached.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

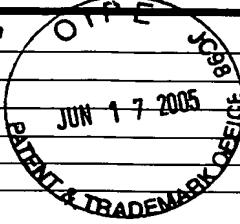
Date June 17, 2005

By 

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Matthew E. Mulkeen
Attorney for Applicants
Registration No. 44,250

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Substitute for form 1449B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: June 17, 2005 (use as many sheets as necessary)					
Sheet	1	of	5	Attorney Docket Number	074129-0510

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
A1	1,995,970			DOROUGH	03/35	
A2	2,362,511			TEETERS	11/44	
A3	2,438,208			FLLACHIONE et al.	03/48	
A4	2,703,316			SCHNEIDER et al.	03/55	
A5	2,758,987			SAIZBERG	08/56	
A6	3,043,782			JENSEN	07/62	
A7	3,092,553			FISHER et al.	06/63	
A8	3,297,033			SCHMITT et al.	01/67	
A9	3,523,906			VRANCKEN et al.	08/70	
A10	3,539,465			Hiestand et al.	11/70	
A11	3,565,869			DePROSPERO	02/71	
A12	3,636,956			SCHNEIDER	01/72	
A13	3,645,911			van BESAUW et al.	02/72	
A14	3,691,090			KITAJIMA et al.	09/72	
A15	3,755,553			SCRIBNER et al.	08/73	
A16	3,755,558			SCRIBNER	08/73	
A17	3,839,297			WASSERMAN et al.	10/75	
A18	3,882,228			BONCEY	05/75	
A19	3,890,283			CASEY et al.	06/75	
A20	3,912,692			CASEY et al.	10/75	
A21	3,922,338			ESTEVENEL et al.	11/75	
A22	3,956,172			SAEKI et al.	05/76	
A23	4,137,921			OKUZUMI et al.	02/79	
A24	4,234,571			NESTOR et al.	11/80	
A25	4,249,531			HELLER et al.	02/81	
A26	4,272,398			JAFFE	06/81	
A27	4,273,920			NEVIN	06/81	
A28	4,384,975			FONG	05/83	
A29	4,389,330			TICE et al.	06/83	
A30	4,479,911			FONG	10/84	
A31	4,555,399			HSIAO	11/85	
A32	4,605,730			SHALABY et al.	08/86	
A33	4,622,244			LAPKA et al.	11/86	
A34	4,637,905			GARDNER	01/87	
A35	4,652,441			OKADA et al.	03/87	
A36	4,667,191			TANAKA et al.	06/87	
A37	4,710,384			ROTMAN	12/87	
A38	4,728,721			YAMAMOTO et al.	03/88	
A39	4,849,228			YAMAMOTO et al.	07/89	

Examiner
Signature

Date
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

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Substitute for form 1449B/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT			
Date Submitted: June 17, 2005		Application Number	10/025,967
(use as many sheets as necessary)		Filing Date	12/26/2001
		First Named Inventor	Shigeru Kamei
		Group Art Unit	Unassigned
		Examiner Name	Unassigned
		Attorney Docket Number	074129-0510
Sheet	2	of	5

U.S. PATENT DOCUMENTS

U.S. Patent Document				
A40	4,917,893		OKADA et al.	04/90
A41	4,954,298		YAMAMOTO et al.	09/90
A42	5,330,767		YAMAMOTO et al.	07/94
A43	5,480,656		OKADA et al.	01/96
A44	5,575,987		KAMEI et al.	11/96
A45	5,631,020		OKADA et al.	05/97
A46	5,643,607		OKADA et al.	07/97
A47	5,716,640		KAMEI et al.	02/98
A48	5,972,891		KAMEI et al.	10/99
A49	6,528,093		KAMEI et al.	03/2003

FOREIGN PATENT DOCUMENTS

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		Office ³	Number ⁴	Kind Code ⁵ (if known)				
	A50	CA	1 169 090		IMPERIAL CHEMICAL INDUSTRIES PLC	02/1982		
	A51	EP	0 107 591	A2	UNITED STATES SURGICAL CORPORATION	05/1984		
	A52	EP	0 145 240	A2	TAKEDA CHEMICAL INDUSTRIES LTD.	06/1985		
	A53	EP	0 178 824	A1	TAKEDA CHEMICAL INDUSTRIES LTD.	04/1986		
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	A55	FR	2,126,270		DU PONT DE NEMOURS & CO.	02/1972		ABS.
	A56	JP	40-500		FUJI PHOTO FILM CO. LTD.	01/1965	Eng. Translation of Detailed Description, Example 1 and Claim	PART.
	A57	JP	43-3017		DASERU LTD.	02/1968	Eng. Translation of First Three Paragraphs and Claim 1	PART.
	A58	JP	55-114193		HITACHI LTD.	05/1972		ABS.
	A59	UK	1,351,409		SCRIBNER	02/72		
	A60	UK	1,405, 108		DE JAEGER ET AL.	12/71		
	A61	UK	2,145,422 A		SANDOZ LTD.	08/84		
	A62	UK	2,246,514 A		SOCIETE DE CONSILIS DE RECHERCHES ET D' APPLICATIONS SCIENTIFIQUES	05/92		

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		Attorney Docket Number	074129-0510
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FOREIGN PATENT DOCUMENTS

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A66	ARSHADY, R., "Preparation of biodegradable microspheres and microcapsules: 2. Polyactides and related Polyesters," <u>Journal of Controlled Release</u> , Vol. 17, pp. 1-20, 1991	
	A67	BAKAN, J. A. et al., "Microencapsulation," <u>The Theory and Practice of Industrial Pharmacy</u> , pp. 384-407, 1970	
	A68	CHANG, T., "Biodegradable Semipermeable Microcapsules containing Enzymes, Hormones, Vaccines, and Other Biologicals," <u>Journal of Bioengineering</u> , 1:25-31, 1976	
	A69	DRESSLER, et al., "Viable Prosthetic Interface," <u>J. Biomed. Mater. Res. Sympomium</u> 1:169-178 (1971)	
	A70	Journal of the Chemical Society of Japan, Industrial Chemistry Section, Volume 72, 1969 pp. 493-499 (English Translation of Sections 2.1 and 3.1)	
	A71	Journal of the Chemical Society of Japan, Industrial Chemistry Section, 68(5), English Abstracts, A52-A53, pp. 983-986 (Japanese Text), 1965	
	A72	KEIPERT, S. et al., "Antiglaumakotosahaltige Ophthalmika mit prolongierter Wirkung auf Basis makromolekularer Hilfsstoffe," <u>Die Pharmazie</u> , pp. 594-595 (English Abstract at page 594), August 1990	

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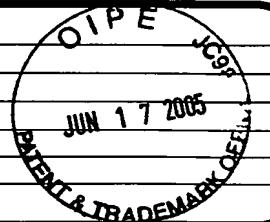
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Sheet		4	of	5	Group Art Unit	Unassigned
					Examiner Name	Unassigned
					Attorney Docket Number	074129-0510



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	A73	KONDO, A., <u>Microcapsule Processing and Technology</u> , Marcel Dekker, Inc., New York, New York (1979), Chapter I, "Microcapsules – General Concepts," pp. 1-10; Chapter III, "Applications and Studies of Microcapsules," pp. 18-26; Chapter IV, "History and Classification of Microencapsulation," pp. 27-34; Chapter X, "Microencapsulation Utilizing In-Liquid Drying Process (Complex Emulsion Method)," pp. 106-120	
	A74	KULKARNI et al., "Biodegradable Poly(lactic acid) Polymers," <u>Journal of Biomedical Materials Research</u> , 5:169-181, 1971	
	A75	KULKARNI et al., "Polyactic Acid for Surgical Implants," <u>Archives of Surgery</u> , 93(5):839-843, November 1966	
	A76	LEWIS, D. et al., "Controlled Release of Bioactive Agents from Lactide/Glycolide Polymers," <u>Biodegradable Polymers as Drug Delivery Systems</u> , pp. 1-41, 1990	
	A77	<u>Microcapsule</u> , Industrial Technology, Library 25, pages 102 (1971)	
	A78	OGAWA, Y. et al, "Controlled Release of LHRH Agonist, Leuprolide Acetate, from Microcapsules: Serum Drug Level Profiles and Pharmacological Effects in Animals," <u>J. Pharma Pharmacol.</u> , PP. 439-444, 1989	
	A79	OGAWA et al., "A new technique to efficiently entrap leuprolide acetate into microcapsules of polylactic acid or copoly (lactic/glycolic) acid." <u>Chem. Pharm. Bull.</u> , Vol. 36, No. 3, pp. 1095-1103, 1988.	
	A80	OKADA, H. et al., "One- and three-month release injectable microspheres of the LH-RH superagonist leuprorelin acetate," <u>Advanced Drug Delivery Reviews</u> , 28:43-70, 1997	
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	A82	OKADA, H. et al., <u>Critical Reviews in Therapeutic Drug Carrier Systems</u> , 12(1):1-99, 1995	
	A83	OMELCZUK, M. et al, "The Influence of Polymer Glass Transition Temperature and Molecular Weight on Drug Release from Tablets Containing Poly(DL-lactic Acid)," <u>Pharmaceutical Research</u> , Vol. 9, No. 1, pp. 26-32, January 1992	
	A84	OMELCZUK, M. et al., "Effect of Thermal Treatment on the Physical-Mechanical and Dissolution Properties of Compacts Containing Biodegradable Polymers," <u>Proceedings of the Ninth International Pharmacuetial Technology Conference</u> Veldhoven, the Netherlands, 1:28-44 (1990)	
	A85	OMELCZUK, M. et al., "The Influence of Thermal Treatment on the Physical-Mechanical and Dissolution Properties of Tablets Containing Poly(DL-Lactic Acid)," <u>Pharmaceutical Research</u> 10(4):542-548 (1993)	

Examiner Signature		Date Considered	
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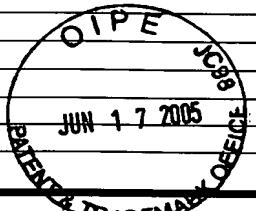
¹ Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

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				First Named Inventor	Shigeru Kamei
				Group Art Unit	Unassigned
				Examiner Name	Unassigned
				Attorney Docket Number	074129-0510



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	A86	PITT, C. et al, "Sustained Drug Delivery Systems, 1. The Permeability of Poly(e-Caprolactone), Poly(DL-Lactic Acid), and Their Copolymers," <u>Journal of Biomedical Materials Research</u> , Vol. 13, pp. 418-507, 1979		
	A87	SANDERS, L. et al, "Controlled Release of a Luteinizing Hormone-Releasing Hormone Analogue from Poly(d, L-lactide-co-glycolide)Microspheres," <u>Journal of Pharmaceutical Sciences</u> , Vol. 73, pp. 1294-1297, September 1994		
	A88	SATO, T. et al, "Porous Biodegradable Microspheres for Controlled Drug Delivery. I. Assessment of Processing Conditions and Solvent Removal Techniques," <u>Pharmaceutical Research</u> , Vol. 5, No. 1, pp. 21-30 January 1988		
	A89	SCHMITT, E. et al., "Importance of Distinct Water Environments in the Hydrolysis of poly(DL-lactide-co-Glycolide)," <u>Macromolecules</u> , 27:743-748, 1994		
	A90	Supplemental Information Disclosure Statement, YAMAMOTO et al, Serial No. 858,040 filed 11/3/87 with the U.S. Patent and Trademark Office		
	A91	<u>The Pharmacopoeia of Japan</u> , Tenth Edition, pp. 16- 21, 1981		
	A92	WANG, H.T. et al., "Influence of formulation methods on the in vitro controlled release of protein from poly (ester) microspheres," <u>Journal of Controlled Release</u> 17:23-31, 1991		
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